

**REMARKS**

**II. Preliminary Matters**

Claims 3, 8, 14, 18 and 20 are amended to insure proper Markush grouping.

Finally, claim 11 is amended to clarify components of the improved composition.

**III. Patentability Arguments**

**A. The Rejections Under 35 U.S.C. § 112, second paragraph, Should Be Withdrawn**

Claims 3, 8, 11, 14, and 20 were rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Claims 3, 8, 14 and 20 are amended by deleting the term "and" preceding the word "capsulation" to clarify that Markush group consists of three different species of capsulation.

Claim 11 is amended to clarify that the improved composition actually contains saw palmetto extract.

In view of the above amendments, the applicants respectfully request that the rejection under 35 U.S.C. §112, second paragraph, be withdrawn.

**B. The Rejections Under 35 U.S.C. § 102(e) Should Be Withdrawn**

Claims 1-3, 6-8, and 11-23 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Mann (U.S. Patent No. 6,231,866, "Mann"). The Applicants respectfully traverse the rejections and request reconsideration and withdrawal of the rejections in view of the following.

The Examiner has characterized the instant claims as being drawn to either an oral composition for treating benign prostatic hyperplasia (BPH) comprising saw palmetto extract and a controlled release system or a method of treating BPH using such a composition.

The Examiner has characterized Mann as teaching saw palmetto extract, termed SAW-MAX. Mann also discloses saw palmetto comprising parts of the entire plant. According to Mann, SAW-MAX is produced by infusing saw palmetto oil into saw palmetto pomace. According to the instant invention, a saw palmetto extract is defined as "the extract of saw palmetto plant in the form of an oil, a water-soluble concentrate, or an alcohol-soluble concentrate of that plant", and is not combined with pomace. Neither does the instant invention utilize the saw palmetto plant *per se*. Therefore, the saw palmetto extract of the

instant invention is different from saw palmetto plant and extract/pomace combinations described in Mann.

Since Mann does not teach the saw palmetto extract of the instant invention, Mann can not properly anticipate the instant invention. Hence, the Applicants request that the rejections under 35 U.S.C. 102(e) over Mann be withdrawn.

The Examiner has also rejected claims 1-3, 6-8, 11, 18-23 under 35 U.S.C. § 102(e) as allegedly being anticipated by Wilding (US 2001/000638 A1, "Wilding"). The Applicants respectfully traverse the rejections and request reconsideration and withdrawal of the rejections in view of the following.

The Examiner has characterized Wilding as teaching a composition with saw palmetto extract for treating benign prostatic hyperplasia. The Examiner is invited to note that Wilding teaches a composition of at least one prohormone, one anti-estrogen (which may be a saw palmetto extract) and an enteric coating. Wilding does not teach compositions of saw palmetto extract without prohormone as does the present application.

Since Wilding and the instant invention are directed to two different compositions, Wilding can not properly anticipate the instant invention. Hence, the Applicants request that the rejections under 35 U.S.C. 102(e) over Wilding be withdrawn.

In view of the foregoing arguments, the Applicants respectfully submit that the rejections under 35 U.S.C. § 102(e) should be reconsidered and withdrawn.

C. The Rejection Under 35 U.S.C. § 103(a) Should Be Withdrawn

Claims 1-23 are rejected under 35 U.S.C. 103(a) as allegedly being obvious over Mann or Wilding, in view of Locke (U.S. Patent No. 6,200,573, "Locke") and Acharya (U.S. Patent No. 5,102,666, "Acharya").

As it has been discussed in Section B, Mann does not teach a saw palmetto extract of the instant invention, but rather Mann teaches saw palmetto plant and extract/pomace combinations. As it has been also discussed in Section B, Wilding does not teach a saw palmetto extract of the instant invention, but rather Wilding teaches a combination of saw palmetto extract and prohormone.

Locke does nothing to remedy the shortcomings of Mann or Wilding. The Examiner has characterized Locke as teaching compositions of saw palmetto extract in combination with an alpha-adrenergic antagonist. Locke does not teach a composition of the instant

invention, which comprises of a saw palmetto extract and a controlled release system or the combinations of saw palmetto extract with antispasmodic drugs as in presented claims.

The Examiner is invited to note that antispasmodic drugs and alpha-adrenergic agonists are not interchangeable groups of drugs. The two groups have different effects and act through different chemical pathways. Therefore, disclosure of  $\alpha_1$ -adrenergic antagonists in Locke does not provide motivation for using phytotherapeutic antispasmodic compounds disclosed in the instant invention. In conclusion, combined Mann, Wilding and Locke do not teach or suggest all elements of the instant invention.

Acharya does nothing to remedy the shortcomings of Mann or Wilding. The Examiner has characterized Acharya as teaching the calcium polycarbophil controlled release composition which may contain peppermint as a flavouring agent. Acharya does not teach or suggest that the calcium polycarbophil controlled release composition can be used with a saw palmetto extract or a combination of saw palmetto extract and an antispasmodic compound. Therefore, there is no motivation to combine teachings of Acharya with teachings of Mann or Wilding and Locke.

Because of the foregoing arguments, the Applicants respectfully submit that the rejections under 35 U.S.C. § 103(a) over Wilding or Mann in view of Locke and Acharya should be withdrawn and withdrawal is requested.

Claims 1-23 stand rejected under 35 U.S.C. § 103(a) allegedly as being obvious over Jia (U.S. 2002/0071869, "Jia"), in view of Mann, Wilding, and Locke, and further in view of Acharya.

Jia does nothing to remedy the shortcomings of Mann and Wilding as set and discussed above. The Examiner has characterized Jia as teaching a composition of a saw palmetto extract in a bioadhesive drug delivery system. The Examiner is invited to note that Jia does not teach that the bioadhesive drug delivery system can be used with an antispasmodic compound. Therefore, Jia, Mann, Wilding, Locke and Acharya, when combined, do not teach or suggest all of the elements of the instant invention.

In view of the foregoing arguments, the applicants respectfully submit that the rejections under 35 U.S.C. § 103(a) should be reconsidered and withdrawn.

### **Conclusion**

The Applicants submit that claims 1-23, as amended in this submission, are in condition for allowance and early notification thereof is solicited. The Commissioner is

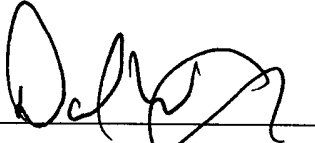
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hereby authorized to charge any additional fees which may be required in the Application to  
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Respectfully submitted,

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